Remarks

Preliminary Remarks

The Applicants have addressed the Patent Office's objection to the specification by providing substitute paragraphs above with the hyperlinks modified to remove the browser executable code per MPEP §608.01. In addition, the paragraph beginning at Page 21, line 21 has been amended to include reference to reference numeral 6 as being an expanded region of Figure 5, and to reference numeral 34 as being interstitial openings.

Claims 1-19 were previously withdrawn as being drawn to a non-elected species.

Applicants have cancelled pending claims 20-22 without prejudice and substitute new claims 23-47 as presented above. All new claims are fully supported by the specification and do not constitute new matter.

All current pending claims (23-47) are fully supported by the specification in general. Specifically, independent claim 23 is generally described throughout the specification with the implantable substrate carrier element described on page 6, line 14 through page 7, line 10 and the sensor element on page 7, lines 11-24. The claims that depend either directly or indirectly from claim 23 are supported by the specification, particularly with respect to the "implantable substrate carrier" element and further limitations thereof, on page 6, line 14 through page 7, line 10. Claim 28 and the claims that depend either directly or indirectly from it are directed to a sensor element that is a plurality of cantilever members, which is described on page 7, lines 17-20 and page 16, line 20 through page 18, line 11. In particular, the claims directed towards the inventive device having cantilever members (claims 28-47) are disclosed on page 16, line 16 through page 21, line 19, and also in Figs. 1-4. The antecedent basis for the biochemical marker element of the claimed invention may be found at page 24, lines 12-19. The claims directed towards the inventive device having binding regions (claims 42-45) are disclosed on page 24, lines 4-22, and also in Figs. 8-10. The method claims (46-47) are generally disclosed throughout the specification and claim use of the claimed device in the method.

Applicants submit that all current claims (23-47) are not subject to the previously stated restriction requirement in that the claims are directed to a medical device that

includes both a substrate carrier element and a sensor element that can detect a physiological event, which can be monitored *ex vivo* to detect the occurrence of that event based upon the state of the sensor element, or to a method using the medical device. Applicants submit that the all claims are sufficiently related so as not to impose an undue burden upon the Office in searching the prior art. In particular, a review of the Manual of Classification, consistent with the preliminary classification in the Official Filing Receipt, the claimed invention would be classified in a two main class and a limited number of sub-classes, namely Class 623, subclasses 1.18, 1.19, 24 or 25 and Class 600, subclasses 410, 420, 421, 431, 481 and 483. Particular dependent claims are directed towards a device that has a sensor element that is either a cantilever member or binding region. With respect to the groups of inventions identified by the Patent Office in previous Restriction Requirement, the Applicants submit that the present claims are directed towards one patentably distinct invention that includes both Species I (cantilever members, Figs. 1-4) and III (biosensors, Figs. 8-10) as identified in the Office Action dated 10/2/2002. Additionally, independent claim 1 is a generic claim that encompasses both Species I and III. Therefore, the Applicants elect the present invention and retain the right to pursue claims drawn to the integral sensor regions or Species II (Figs. 5-7) in a later-filed divisional application.

Arguments

The rejection under 35 USC §112 is moot in view of the amendments presented herein.

The rejection under 35 USC 102(b) over Flomenblit et al. (US Pat. No. 5,562,641) should be withdrawn because Flomenblit et al. fails to disclose all elements of the invention as claimed in the presently pending claims. Flomenblit et al. is concerned with and discloses a medical stent made of a two way shape memory alloy with two transition temperatures that facilitates removal, which is starkly different from the present invention that includes a sensor to detect *in vivo* physiological events *ex vivo*. Furthermore, beyond failing to disclose a sensor, the stent disclosed by Flomenblit only reacts to temperature changes due to its shape memory properties.

Flomenblit et al. fails to disclose the sensor element of the invention and methods of detecting a clinically physiological event ex vivo using the same sensor element, and therefore fails to anticipate the present claims. It is respectfully submitted that the Examiner is incorrect in concluding that Flomenblit et al. discloses a sensor when citing to col. 2, lines 62-66. In fact, those lines only disclose the "two-way shape memory alloy" such as Ni-Ti, Ni-Ti-X (X being V, Co, Cu, Fe), Cu-Al-Ni, or Cu-Zn-Al. The two phase transition property is disclosed to allow for removal of the stent or for changing its position by introduction of cooling liquid. See col. 4, lines 53-58. Moreover, the Examiner's reference to use of RF irradiation as an exogenous energy stimulus (col 5, lines 48-52) is similarly misplaced because the RF energy is employed to inductively heat the stent element, causing the nitinol to heat and excursion beyond a transition temperature to enlarge the stent. There is no disclosure in Flomenbilt, et al. that the stent is able to return a signal to an *ex vivo* detector to provide information concerning its *in vivo* state. Thus, Flomenbilt, et al. is devoid of any teaching, express or implied, of a sensor element, whether a binding region or a cantilever member, anywhere in Flomenblit et al.

Accordingly, the Applicants respectfully request withdrawal of 102(b) rejection over Flomenblit et al.

Conclusion

Based upon the foregoing amendments and arguments, pending claims 23-47 are in condition for allowance over the art cited and of record and Applicants respectfully request allowance of these claims and issuance of a Notice of Allowability.

This response is timely as it is submitted with a Request for Extension of Time and an Amendment Transmittal along with appropriate fees, however, the Commissioner is hereby authorized to charge any fees which may be required, or credit any overpayment, to Rosenbaum & Associates, P.C. deposit account No. 18-2000.

Should the Examiner require any further information or wish to discuss any aspect of this Response, the Examiner is encouraged to telephone the undersigned at the telephone number set forth below.

Respectfully submitted,

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